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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,673	12/21/1999	D LANSING TAYLOR	97223D	3907

20306 7590 04/04/2005

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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,673

Applicant(s)

TAYLOR, D LANSING

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The Remarks filed 20 August 2004 is acknowledged and has been entered.

Priority

2. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. Although the amendment to the specification filed 20 May 2003 provides a statement indicating priority to application serial number 08/810,983, the application is now US Patent 5,989,835. The phrase "now US Pat. No. 5,989,835" should be added after the term "February 27, 1997," in the specification.

Claim Objections

1. Claim 1 is objected to because of the following informalities: The term "comprise" in line 4 seems like it should be "comprises". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claims 16 (line 1) and 17 (line 6), the phrase "controlled array of cell types" is vague and indefinite. The specification does not provide a definition for the phrase and it is unclear as to how the term "controlled array" limits the term "cell types". How are the cell types controlled? Are the cell types chosen depending on which cell binding sites are placed on the well, or is another situation claimed?

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al (US 5,846,708) in view of Cherukuri et al (US 5,980,704).

In the instant claims, Hollis et al reference teaches a sequencer 10 (i.e. base having a surface) with an array of test sites 12, wherein each test site contains a plurality of probes 22 that bind to cell targets, and wherein probes in respective test sites differ in known sequence for simultaneous detection of a plurality of different targets (i.e. non-uniform micro patterned chemical array comprises multiple cell binding sites; more than one cell type). See column 4, lines 23-28 and 32-45; and Figure 1. In addition, Hollis et al reference teaches that test sites 12 contain channels (i.e. well) wherein the probes 22 are immobilized therein. See column 4, lines 34-35 and Figures 2-4. With respect to claims 16-17, although Hollis et al reference does not explicitly teach "a controlled array of cell types on the wells, wherein the cell type on an individual well is dependent upon the cell binding specificity of the cell binding sites in the well", since Hollis et al reference teaches that probes on each site can bind to different targets and that cells are targets, as stated above, it is necessarily required that different types of cells are present at each test site.

However, Hollis et al reference fails to teach a fluid delivery system, wherein said fluid delivery system comprises a chamber that mates with the base, wherein the chamber comprises a plurality of domains matching the wells on the surface of the base, and microfluidic channels that supply fluids to the domains.

Cherukuri et al reference teaches a modular configuration wherein the a center distribution plate with a plurality of reservoirs and microchannels (i.e. fluid delivery system comprises a chamber; microfluidic channels) is defined into a plurality of sectors, each sector being directly positioned above a reaction cell located on the bottom cell plate (i.e. comprises a plurality of domains matching the wells on the surface of the base; mates with the base), in order to provide a proper control and delivery system for regulating and distributing minute amounts of reagents to the reaction cells. See column 2, lines 6-9; and column 3, lines 7-10 and 21-30.

With regards to claims 9 and 18, Cherukuri et al reference teaches reservoirs, as stated above. Although Cherukuri et al reference does not explicitly teach that the reservoirs are "raised", since the reservoirs are on a plate that is above the bottom cell plate, it is considered to be on a higher level than the bottom cell plate and are therefore raised.

With regards to claims 10 and 19, Cherukuri et al reference teaches that the center distribution plate contains overflow feeds 380 (i.e. microfluidic channels that remove excess fluid from the domains). See column 7, lines 16-21 and Figure 3.

With regards to claims 11 and 20, Cherukuri et al reference teaches column reservoirs coupled to microchannels (i.e. individual microfluidic channel) that deliver reagents to a location vertical from the column reservoirs, wherein column reservoirs are only capable of delivering its reagents to the reaction cells that are situated vertically from the column reservoirs, in order to permit a large array of parallel tests to be

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conducted simultaneously (i.e. supplies fluid to a single domain, to provide separate fluid flow to each domain). See column 3, lines 13-15 and column 8, lines 33-37.

With regards to claims 12 and 21, Cherukuri et al reference teaches a plurality of dams (i.e. plug) that prohibit reagents from entering a cell feed without the activation of miniature pumps, which allows reagents to be drawn over the dams from the microchannels and deposited into the reaction cells. See column 3, lines 24-30.

With regards to claims 13 and 22, Cherukuri et al reference teaches that the microchannels are etched on both sides of the center distribution plate (i.e. microfluidic channel extends from each domain to an edge of the chamber). See column 3, lines 7-10 and Figure 3.

With regards to claims 14-15, Hollis et al reference teaches an array of test sites 12 and that test sites differ in probes that bind to cells for simultaneous detection of a plurality of different cell targets (i.e. array of cells on the wells; wells in total comprise cell binding site for more than one cell type), as stated above. See column 4, lines 23-24 and 37-45.

Response to Arguments

8. Applicant's arguments, see pages 3-5 of the Remarks, filed 20 August 2004, with respect to the rejection(s) of claim(s) 1 and 9-22 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

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However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

In the rejection supra based on 35 USC 103, Hollis et al reference provides teaching of step (a) in independent claim 1 and steps (a)-(b) in independent claim 17. However, Hollis et al reference lacks teaching of step (b) in claim 1 and step (c) in claim 17. Cherukuri et al reference teaches the lacking steps with the motivation of providing proper control and delivery system for regulating and distributing minute amounts of reagents to the reaction cells. The dependent claim limitations 9-10 and 18-22 are all either taught by Hollis et al and Cherukuri et al.

Conclusion

9. No claims are allowed.

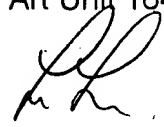

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641


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03/30/05